IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/646,970
Applicant	:	Carol J. Phelps
Conf. No.	:	3048
Filed	:	August 21, 2003
TC/A.U.	:	1632
Examiner	:	Magdalene K. Sgagias
Title	:	Porcine Animals Lacking Any Expression of Functional Alpha 1,3 Galactosyltransferase
Docket No.	:	10758.105009 REV1004
Customer No.	:	20786

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

November 9, 2009

Declaration under 37 C.F.R. §1.131

1. I am the sole named inventors of the invention claimed in the above-referenced patent application.
2. In a final Office Action mailed by the U.S. Patent and Trademark Office on June 2, 2009, the Examiner rejected Claims 1-8, 13, 17-18, 43, 48, 60 and 62 under U.S.C. 102(e) as anticipated by Hawley, et al. (US Publication No. 2006/0242722, filed August 14, 2003 and claiming priority to U.S. Provisional Application No. 60/403,405, filed August 14, 2002).
3. I conceived of the pigs lacking α(1,3)galactosyltransferase (GT) before August 14, 2002. Furthermore, these pigs were actually born prior to the reference date. The work leading to this invention was carried out in the US at PPL Therapeutics Inc.'s US subsidiary located in Blacksburg, Virginia.
4. Exhibits 1-3 are submitted to support the actual reduction to practice of the invention prior to the reference date. Exhibit 1, attached to this declaration, is a press release from PPL Therapeutics that notes that double knockout pigs lacking both copies of the GT gene were born on July 25, 2002. These pigs were thus actually reduced to practice prior to August 14, 2002.
5. Exhibit 2 shows images of lectin staining of liver of wild type pigs and the liver of one of the pigs born on July 25, 2002 (coded "761-1"). Lectin stains to the α-(1,3)-galactose sugar residue in cell components. In essence, the image shows a complete lack of staining in the

761-1 pig (right panels), but diffuse sinusoidal (small arrow upper left), venous endothelial (large arrow upper left), and biliary epithelial cell (large arrow bottom left) in the wild type pig. The higher magnification of 761-1 (lower right) shows in greater detail the absence of biliary epithelial cell or venous endothelial cell staining.

6. Exhibit 3 is a copy of Phelps, et al. (2003) *Science* 299:411-414 and its supplementary materials (see reference on page 414), which includes additional studies showing that cells from the animals born prior to August 14, 2002 did not express any functional GT, as recited in the claims.
7. I declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true. I acknowledge that willful false statements are punishable by fine or imprisonment or both under 18 U.S.C. §1001 and may jeopardize the validity of the application or any patent issuing thereon.

Carol J. Phelps

Nov. 9, 2009
Date